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FDA's OK will propel Lynch into sales push

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Executive Q&A

Sam Lynch parlayed a research discovery he helped to make as a post-doctoral fellow at Harvard into BioMimetic Therapeutics Inc., one of the Nashville area's best corporate success stories in life sciences

Now, with U.S. Food and Drug Administration approval pending for its drug-medical device known as Augment, which speeds the growth of bone tissue after foot and ankle surgery, Lynch and his team hope to take the Franklin-based biotech firm to the next level.

Lynch spoke with *Tennessean* health-care reporter Getahn Ward about how to recruit more biotech companies to the Nashville area, and about BioMimetic's plans.

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Sam Lynch, president and CEO of BioMimetic Therapeutics, is planning for rapid growth if the FDA approves its Augment bone growth product. (JAE S.

What is the significance of your Augment product and how did the concept evolve?
BioMimetic is focused in an area called muscular skeletal tissue regeneration or regenerative medicine. Our focus is to develop products that help the body heal faster and better. This area of research came out of early research that I did while at Harvard University as a graduate student and post-doctorate fellow.

Our first orthopedic product is called Augment bone graft, and as the name implies it's meant to augment or enhance the repair of bones and bone injuries.

What evidence is there that Augment actually improves patient outcomes and is safe?
Currently, significant bone injuries and bone fusions are often treated by harvesting bone from another part of the body of the patient, but that often requires a second surgical procedure to harvest the bone and then transplant it to the site of the bone injury.

Our product, Augment, is a completely synthetic product that can be taken off the shelf by the surgeon and is just as effective as the bone transplanted from another part of the body.

But it eliminates the need for the second surgery and thereby eliminates the pain and potential infection and other complications that arise from having to harvest bone from another part of the body.

Broadly speaking the regenerative medicine market opportunity … just within orthopedics is roughly $4 billion a year. Our first specific applications in the area of facilitating bone healing — that's about $1.7 billion a year.
Our first product that we successfully developed — and received FDA approval for — was for the treatment of periodontal bone defects in the jaws. We started there because my medical training is as a periodontist with a doctorate in medical sciences. We successfully commercialized that product and then sold that business for $80 million to $90 million to reinvest the proceeds into developing additional products in the broader orthopedic market.

Does your business stand to benefit from an aging baby boomer population?
Certainly, the aging of the baby boomers increases the need for regenerative products in general. Also, we believe that orthopedics is transitioning from being primarily a field of medicine in which the surgeon cuts out the damaged bone and replaces it with a metal prosthetic, for example, to a more regenerative state in which physicians try to repair and regenerate the natural tissue.

How much competition is there in the regeneration marketplace?
Medtronic Sofamor Danek in Memphis has one of the only competitive products to what we're developing. Their product called INFUSE is meant primarily to promote spine fusions and sells about $800-plus million a year.

So, that clearly suggests there's a very large clinical need for these kinds of products. We're looking at foot and ankle fusions, which are procedures that are done to treat chronic pain, often as a result of post-traumatic arthritis. They have said they're

potentially looking to test their product in the foot and ankle, but that could certainly be probably several years before it would be available in that indication.

What's the relative cost of your product compared to other standard treatments?
We've done some health economics studies … and we're estimating that Augment will save the health-care system potentially 20 percent or more over both INFUSE, as well as atogenous bone graft (where bone is taken from elsewhere). Specifically, one might think that bone taken from the patient's body might be free because it's taken from the patient's body. But in fact, the cost of the additional operating room time, the additional blood loss, the additional anesthetics and analgesics — the pain medication — and the cost of complications that can arise all add significantly to those costs.

How much does BioMimetic have riding on the FDA's approval of Augment? How confident are you of the outcome?
The pending approval of Augment bone graft for orthopedic bone grafting applications will be a major event for the company. We believe it's a very unique product that will benefit a lot of patients, and that will take BioMimetic to the next level in terms of its growth.

We expect the product to be approved by the FDA because we've conducted one of the largest randomized controlled clinical studies that has been conducted in this field of regenerative medicine, particularly in orthopedics.

Also, we have about $70 million in cash, which we believe will be sufficient to get the product approved and to launch sales.

What are your plans for taking it to market and building a sales force?
Our plan right now is to build a hybrid sales force in orthopedics where we would look at hiring 15 or 20 direct sales management personnel, plus an additional 80 or so independent sales reps throughout the country.

We will hire some of the sales management personnel in the second half of this year as we approach the FDA advisory panel meeting, but we'll certainly wait to hire the majority of the sales team until after the meeting, which again we hope will be around the end of this year.

How does health-care reform, which includes a 2.3 percent excise tax on medical devices starting in 2013, affect BioMimetic?
The additional taxes on medical devices will certainly be something that we have to take into account as we look at the strategy for growing our business.

On the other hand, the positive aspect of health reform is the 30 million or so additional patients that will have insurance coverage and will have better access to sophisticated treatments such as ours.

What's the missing ingredient for building a more robust life-sciences industry in Nashville?
Nashville has a lot of the key components but is missing really an ability to align and connect those components in the optimum way to really create a critical mass for growth.

Tennessee, in general, and specifically Middle Tennessee need stronger associations to advocate and organize the life-sciences industry in a more cohesive way … to attract investments and develop the work force. One of the biggest hurdles that life sciences companies have is access to a skilled workforce, and that's why we formed the BioTN foundation … to promote workforce development for life sciences companies.

The Cool Springs Life Sciences Center building, which has just been completed in the last few months, now really offers an asset, which we hope can be used to help recruit additional life-sciences companies to the area. That, together with our efforts to enhance the availability of a skilled work force in the life sciences, does provide a good foundation for additional growth. And that wasn't available frankly until the last few months.

What's been your experience so far as you recruit people to fill job openings here?
We certainly have found a lot of our work force here locally, but we've also recruited a lot of talent from out of state to BioMimetic. And we find that once you get the prospective out-of-state employee here to see the area, there's a very high success rate of recruiting those individuals, even competing with companies on the East and West coasts.